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Terms: name(trigg county hospital) (Edit Search)

*2004 U.S. App. LEXIS 21437, **

Tina K. Field; Norman Thomas Field, Jr., Plaintiffs-Appellants/Cross-Appellees, v. **Trigg County Hospital,** Inc., Defendant, William B. Anderson, M.D., Defendant-Appellee/Cross-Appellant.

Nos. 02-6440/6517

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

2004 U.S. App. LEXIS 21437

August 10, 2004, Argued
October 15, 2004, Decided
October 15, 2004, Filed

PRIOR HISTORY: [*1] Appeal from the United States District Court for the Western District of Kentucky at Paducah. No. 99-00207. Edward H. Johnstone, District Judge.

DISPOSITION: Vacated and remanded for new trial. Appellee's cross-appeal dismissed as moot.

CASE SUMMARY

PROCEDURAL POSTURE: Appellant patient sought review of a judgment from the United States District Court for the Western District of Kentucky at Paducah entered upon a jury verdict in favor of appellee physician in a medical malpractice action. The patient challenged the district court's denial of her motion for a new trial, and the physician cross-appealed the district court's denial of attorney fees and costs.

OVERVIEW: The patient sought care from the physician at a hospital emergency room for a copperhead snake bite. When the patient's condition worsened, she sought treatment at a military hospital emergency room and ultimately the patient's leg was amputated below the knee. The court agreed that the patient was entitled to a new trial because the district court improperly admitted prejudicial hearsay evidence when it permitted the physician to testify about the statements made by two unnamed, undisclosed university hospital physicians with whom the physician allegedly consulted concerning the patient's medical care. The court found that the statements were classic hearsay because they served the purpose of exposing the jury to the approving words of two purported experts as to the physician's standard of care. Further, the testimony was not admissible under Fed. R. Evid. 803(4) as determined by the district court because Rule 803(4) was limited to statements made by the person seeking medical treatment. The court found that the substance of the statements, combined with the air of prestige and expertise attributed to their anonymous sources, rendered them highly prejudicial to the patient.

OUTCOME: The court vacated the jury's verdict and remanded the case to the district court for a new trial. The court dismissed the physician's cross-appeal as moot.

CORE TERMS: admonition, hearsay, right foot, emergency room, toxicologist, standard of care, snake bite, new trial, doctor, copperhead, antivenin, leg, hearsay exception, admissible, treating, pulse, snake, bite, proper care, highly prejudicial, hearsay evidence, medical care, vacate, appropriately, administered, harmless, patient, advice, erroneous admission, claim of error

LexisNexis(R) Headnotes ◆ Hide Headnotes

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion

EXHIBIT
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Civil Procedure > Relief From Judgment > Motions for New Trial

HN1 The appellate court reviews a district court's denial of a motion for a new trial under an abuse of discretion standard. More Like This Headnote

Civil Procedure > Appeals > Standards of Review > De Novo Review

Evidence > Hearsay Rule & Exceptions > Hearsay Rule Components

Evidence > Procedural Considerations > Rulings on Evidence

HN2 The appellate court reviews de novo a district court's conclusions of law, such as whether evidence offered at trial constituted hearsay within the meaning of the Federal Rules of Evidence. More Like This Headnote

Evidence > Hearsay Rule & Exceptions > Physical Condition & Medical History

HN3 See Fed. R. Evid. 803(4).

Evidence > Hearsay Rule & Exceptions > Physical Condition & Medical History

HN4 The rationale behind the Fed. R. Evid. 803(4) exception to the hearsay rule is that statements made by an individual to physicians for purposes of diagnosis or treatment are considered exceptionally trustworthy because the declarant has a strong motive to tell the truth in order to receive proper care. As such, courts have interpreted the exception to be limited to statements made by the one actually seeking medical treatment or care. More Like This Headnote

Civil Procedure > Appeals > Standards of Review > Harmless & Invited Errors

Evidence > Procedural Considerations > Rulings on Evidence

HN5 The appellate court will vacate a jury's verdict based on a district court's erroneous admission of hearsay evidence only if the testimony's admission amounted to more than harmless error. More Like This Headnote

Civil Procedure > Appeals > Standards of Review > Harmless & Invited Errors

Evidence > Procedural Considerations > Rulings on Evidence

HN6 In close cases, the improper admission of prejudicial evidence is all the more damaging. More Like This Headnote

Civil Procedure > Appeals > Reviewability > Preservation for Review

Evidence > Procedural Considerations > Objections & Offers of Proof

Evidence > Procedural Considerations > Rulings on Evidence

HN7 According to Fed. R. Evid. 103(a)(2), once the court makes a definitive ruling on the record admitting or excluding evidence, either at or before trial, a party need not renew an objection to preserve a claim of error for appeal. More Like This Headnote

COUNSEL: ARGUED: Dan L. Nolan, Jr., BATSON, NOLAN, BRICE, HARVEY & WILLIAMSON, Clarksville, Tennessee, for Appellants. E. Frederick Straub, Jr., WHITLOW, ROBERTS, HOUSTON & STRAUB, Paducah, Kentucky, for Appellee.

ON BRIEF: Dan L. Nolan, Jr., Suzanne G. Pearson, BATSON, NOLAN, BRICE, HARVEY & WILLIAMSON, Clarksville, Tennessee, W. Douglas Myers, William J. Sweeten, DEATHERAGE, MYERS, SELF & LACKEY, Hopkinsville, Kentucky, for Appellants. E. Frederick Straub, Jr., Joe H. Kimmel, III, WHITLOW, ROBERTS, HOUSTON & STRAUB, Paducah, Kentucky, for Appellee.

JUDGES: Before: SILER, MOORE, and COLE, Circuit Judges. COLE, J., delivered the opinion of the court, in which MOORE, J., joined. SILER, J. (p. 8), delivered a separate dissenting opinion.

OPINIONBY: R. GUY COLE, JR.

OPINION: R. GUY COLE, JR., Circuit Judge. Plaintiffs-Appellants, Tina and Norman Field, appeal the district court's denial of their motion for a new trial after a jury returned a verdict in favor of Defendant-Appellee, Dr. William B. Anderson, following a **[*2]** trial for medical malpractice in federal court based on diversity jurisdiction. Plaintiffs contend that they are entitled to a new trial because the district court improperly admitted prejudicial hearsay evidence when it permitted Dr. Anderson to testify about the statements made by two unnamed, undisclosed physicians with whom he allegedly consulted concerning Tina Field's medical care.

Because the statements of the two unknown physicians were classic hearsay and do not fall into any of the hearsay exceptions contained in the Federal Rules of Evidence, and because the statements' admission was highly prejudicial and more than mere harmless error, we VACATE the jury's verdict and REMAND the case to the district court for a new trial.

I. BACKGROUND

A. Factual Background

At approximately 9:20 p.m. on September 1, 1998, Tina Field sought treatment at the Trigg County Hospital emergency room, in Cadiz, Kentucky, immediately after being bitten twice in her right foot by a copperhead snake. Defendant-Appellee, William B. Anderson, was the physician on call when Field arrived at the hospital. Dr. Anderson is a family practitioner with a solo practice, but he also works shifts at **[*3]** the Trigg County Hospital emergency room. Upon learning that a snake bite victim was coming to the emergency room, Dr. Anderson reviewed the emergency room textbook concerning the treatment of snake bites and called a hospital in Murray, Kentucky, to have antivenin delivered to Trigg County Hospital. The antivenin arrived shortly after Tina Field checked into the emergency room. Dr. Anderson had experience with only one venomous snake bite prior to treating Tina Field's injury, and he had no experience administering antivenin.

When she arrived at the emergency room, Tina Field reported that she felt sick to her stomach, faint, dizzy, and numb, and Dr. Anderson noted significant swelling in her right foot and that the foot was warm.

Dr. Anderson determined that Field had a "wet" copperhead snake bite, which meant that there had been envenomation. His plan was to monitor her, administer intravenous fluids and a tetanus shot, and look for any progression of the bite's severity. Dr. Anderson checked on Field periodically during the night, but did not give her any antivenin. When Dr. Anderson next saw her, at 9:00 a.m. on September 2, Field had swelling above her right knee, and **[*4]** her right foot was becoming cold and had a bluish color to it.

At 5:00 p.m. on September 2, Field complained of pain in her right big toe and coldness in her right foot. At this point, Nurse Stephen P'Poole checked Field's right foot for a pulse, but did not feel one. As a result, P'Poole called Dr. Anderson. At no time after 5:00 p.m. did Tina Field have a pulse in her right foot.

Three hours later, at 8:10 p.m., Dr. Anderson made his first call for assistance. He phoned an attending emergency room physician at the Vanderbilt University Medical Center, who then referred him to a Vanderbilt toxicologist. The Vanderbilt physicians were never deposed and they never testified at trial.

Indeed, their identities, names, and credentials remain completely unknown. Nevertheless, Dr. Anderson was permitted to testify at trial that he telephoned these individuals and gave them a patient history and condition assessment of Tina Field; however, there was no evidence that Dr. Anderson told the Vanderbilt physicians that Tina Field lacked a pulse in her right foot. Moreover, Dr. Anderson was permitted to testify-over Plaintiffs' objections-as to what the Vanderbilt physicians said over the **[*5]** telephone. According to Dr. Anderson, the Vanderbilt emergency room physician and toxicologist told him that he was "doing everything appropriately," that "they would be doing the same thing;" and that the main treatment is to elevate and monitor the leg. Dr. Anderson's testimony concerning the Vanderbilt physicians' alleged statements is the crux of this appeal and will

be discussed in more detail below.

Tina Field remained in the Trigg County Hospital, under the care of Dr. Anderson, through September 6. On that date, despite Field's foot remaining cool and without a pulse, Dr. Anderson believed the snake bite was improving, discharged Field from the hospital, and instructed her to keep her right leg elevated and to return for an appointment two days later. At the September 8 checkup, Field's foot was still cool and there was still no pulse in her right foot.

The Fields were growing more concerned about Ms. Field's condition and so, on September 9, they sought treatment at the Blanchfield Army Hospital emergency room in Fort Campbell, Kentucky. (Ms. Field was entitled to medical care at the military hospital pursuant to benefits received by her husband, who is retired from the **[*6]** United States Army). Tina Field stayed at Blanchfield until September 15, when she was transported by a medical helicopter to Wright-Patterson Air Force Base in Dayton, Ohio. Upon her arrival at Wright-Patterson, Field's treating physician, Dr. Christopher Spieles, knew that Ms. Field was in need of some sort of amputation. In an effort to lessen the amount of amputation, Field underwent hyperbaric dives-which are designed to deliver large amounts of oxygen to body tissue-in an attempt to revive the tissue in her right foot. Unfortunately, these treatments did not improve her condition. As a result, Field's right foot was surgically amputated on October 1, 1998. During the surgery, Dr. Spieles observed that the condition of Field's leg tissue was such that a second surgery would be necessary. Accordingly, on October 6, 1998, Field underwent a below-the-knee leg amputation. She subsequently required two additional surgeries to modify the stump in order to accommodate a prosthetic device.

B. Procedural History

The Fields filed this diversity action against Trigg County Hospital and Dr. Anderson on February 5, 1998, alleging malpractice and negligence. The hospital settled with **[*7]** the Fields prior to trial and was dismissed as a defendant. A jury trial concerning the claims against Dr. Anderson commenced on March 4, 2002, and lasted four days. At issue was whether Dr. Anderson breached the standard of care for treating a copperhead snake bite. Plaintiffs alleged that Anderson was inexperienced in treating venomous snake bites and that Tina Field should have been transferred to physicians and facilities more capable of treating her serious injury.

Each side presented three expert medical witnesses concerning the standard of care administered by Dr. Anderson. In addition, as explained above, Dr. Anderson testified that on September 2, 1998, he telephoned the Vanderbilt University Medical Center to seek advice concerning how to treat Tina Field's snake bite. At this point in the trial, Anderson's attorney halted Anderson's direct examination to consult with the trial judge about the proper scope of the testimony he could elicit from Anderson-that is, whether Anderson could relay to the jury what the Vanderbilt physicians told him on the telephone.

At a hearing outside the presence of the jury, the trial judge stated that he would permit Anderson to testify **[*8]** as to the Vanderbilt physicians' statements. It is difficult to discern the rationale used by the district court to admit the testimony; and, at times-as is evident from the hearing transcript excerpted below-the rationale appears somewhat contradictory. The judge seems to have ruled that the testimony was admissible under the hearsay exception in Fed. R. Evid. 803(4), which permits statements made for purposes of medical diagnosis or treatment to be admitted for the truth of the matter asserted. (In its order denying Plaintiffs' motion for a new trial, the district court again appears to have relied on Fed. R. Evid. 803(4) to justify the statements' admission). Subsequently, however-and this is what leads us to find the district court's rationale somewhat confusing-the court instructed the jury that the statements were not to be considered for their truth (that is, that Dr. Anderson was administering proper care). The Fields's attorney objected on the grounds that the testimony was classic hearsay, that it did not fall under the Fed. R. Evid. 803(4) exception, and that Vanderbilt **[*9]** physicians' statements constituted expert opinions, which, if admitted, would go wholly unchallenged because the physicians could not be cross-examined.

Following is the colloquy among the parties and the judge-outside the presence of the jury-during which time the court announced its somewhat confusing ruling that it would allow Anderson to

testify as to the Vanderbilt physicians' statements:

THE COURT: Well, there's a lot, I mean that fits into the, into the . . . 803(4) rule, but I think [Anderson] can state what he heard. It's not for the proof of what he heard, but statements of what he heard and relied upon. It's been an issue in this case right along, so I'm going to let it come in.

PLAINTIFFS: Well, I think the jury ought to be given an admonition what Vanderbilt has told him is not to be considered for a purposes of determining whether that's appropriate care or not.

THE COURT: You can all work it out. Let me pass on that one when it's coming in.

PLAINTIFFS: I think [Defendant's counsel is] getting ready to right now.

DEFENDANT: I'm getting ready to ask right now.

THE COURT: I'm going to let [Anderson] say it. That the information received, is it not?

DEFENDANT: **[*10]** That's correct.

THE COURT: Whether it's good medical care or not.

DEFENDANT: That's right.

THE COURT: Go ahead.

Back before the jury, Dr. Anderson then testified as to what he told the Vanderbilt emergency room physician and toxicologist and what they, in response, told him. The relevant testimony was as follows:

DEFENDANT'S COUNSEL: Dr. Anderson, when you talked to the physicians at Vanderbilt, did they tell you anything or did you get any information from them?

ANDERSON: Yeah, both the ER doctor and the toxicologist that I talked to said essentially the same thing . . . . As far as the leg goes, they said that they never administer antivenin to copperhead snake bites and certainly would not, you know, this, you know, far, you know, into the course. They felt like, you know, that we were doing everything appropriately, you know, keeping the leg, you know, elevated, you know, that you would normally expect for the swelling to progress over 24 to 48 hours and then she would start to, you know, show some improvement, you know from there. So that, you know, the ER doctor said that and he said he would get a toxicologist to talk to me, too, to, you know, to get, you know, this person's **[*11]** opinion. So, you know, I went back and talked to Mr. Field and told him the information that we had so far and that I was waiting on the call from the toxicologist. And then in a little while the toxicologist called back and again I presented the, you know, the whole history to her and, you know, she said eventually, you know, the same thing . . . [that] the leg was doing what would be expected with a copperhead snake bite, that she does not administer antivenin, you know, to copperhead snake bites and, and that the main treatment is keeping it elevation, you know, keeping it elevated, monitoring and giving supportive treatment and that they would be doing the same thing. She did say that she would be willing to take, you know, if the patient and the family wanted to come up there, but she felt like they would not do anything different.

II. DISCUSSION

At issue is: (1) whether the district court erred by permitting Dr. Anderson to testify about what he was told by the Vanderbilt physicians, and (2) if so, whether that error was so prejudicial as to require us to vacate the jury's verdict and remand the case for a new trial.

HN1 We review a district court's denial of a motion for **[*12]** a new trial under an abuse of discretion standard, *Tompkin v. Philip Morris USA, Inc.*, 362 F.3d 882, 891 (6th Cir. 2004), although HN2 we review de novo a district court's conclusions of law, such as in this case, whether evidence offered at trial constituted hearsay within the meaning of the Federal Rules of Evidence. *Hancock v. Dodson*, 958 F.2d 1367, 1371 (6th Cir. 1992) (citation omitted).

Defendant contends that the statements of the Vanderbilt physicians-admitted through Dr. Anderson's testimony-were not hearsay because they were not used to prove the truth of the matter asserted (the matter asserted being that Dr. Anderson was "doing everything appropriately" and that "they would not do anything different."). Defendant contends that the statements were elicited to prove simply that Dr. Anderson provided proper care by "consulting with other physicians who were better versed in the field of toxicology." (Appellee's Brief, at 16). As a preliminary matter, that argument fails because the qualifications-indeed, the very identities-of the Vanderbilt physicians are not even known. But more importantly, the argument is simply not credible. The fact that **[*13]** a conversation took place between Dr. Anderson and the Vanderbilt physicians is not hearsay, and the simple fact that a consultation took place could have been elicited easily by Defendant's counsel without revealing the substance of the Vanderbilt physicians' responses. (Indeed, that is precisely what happened prior to Defendant's counsel pausing during his direct examination of Dr. Anderson to consult with the district judge whether or not he could proceed to question Dr. Anderson about the substance of the statements). Therefore, the only possible purpose for taking the additional step of telling the jury what was allegedly said by the Vanderbilt physicians was to expose the jury to the substance of those statements and persuade the jury of their truth-namely, that Dr. Anderson was "doing everything appropriately." The statements were hearsay because they went well beyond conveying that Dr. Anderson sought out a consultation to the entirely self-serving purpose of exposing the jury to the approving words of two purported experts from a purportedly esteemed medical institution.

Defendant next contends that even if the testimony was offered for the truth of the matter asserted, it **[*14]** was admissible pursuant to the hearsay exception contained in Fed. R. Evid. 803(4), which permits the admission of statements made for purposes of medical diagnoses or treatment. The rule states in relevant part:

HN3 The following are not excluded by the hearsay rule . . . . Statements made for purposes of medical diagnosis or treatment describing medical history, or past or present symptoms, pain or sensations, or the inception or general character of the cause or external source thereof insofar as reasonably pertinent to diagnosis or treatment.

HN4 The rationale behind this exception is that statements made by an individual to physicians for purposes of diagnosis or treatment are considered exceptionally trustworthy because the declarant has a strong motive to tell the truth in order to receive proper care. *White v. Illinois*, 502 U.S. 346, 355-56, 116 L. Ed. 2d 848, 112 S. Ct. 736 (1992).

As such, courts have interpreted the exception to be limited to statements made by the one actually seeking medical treatment or care. *See Stull v. Fuqua Inds., Inc.*, 906 F.2d 1271, 1273-74 (8th Cir. 1990) ("To fall within the exception [of Fed. R. Evid. 803(4) **[*15]**], the statement must be obtained from the person seeking treatment, or in some instances from someone with a special relationship to the person seeking treatment, such as a parent."); *Bulthuis v. Rexall Corp.*, 789 F.2d 1315, 1316 (9th Cir. 1985) ("Rule 803(4) applies only to statements made by the patient to the doctor, not the reverse."); *see also Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 564 (7th Cir. 1996) (holding that statements made by a doctor to a patient are not admissible under

Fed. R. Evid. 803(4) because the rule does not except statements by the person providing medical care). We agree that the hearsay exception set forth in Fed. R. Evid. 803(4) applies only to statements made by the one actually seeking or receiving medical treatment. Accordingly, the Vanderbilt physicians' statements-as statements made by consulting physicians to the treating physician-are not admissible pursuant to the Fed. R. Evid. 803(4) hearsay exception.

Having determined that the statements were hearsay and that they do not fall under the hearsay **[*16]** exception set forth in Fed. R. Evid. 803(4), we now turn to the question of the statements' impact. HN5 We will vacate a jury's verdict based on a district court's erroneous admission of hearsay evidence only if the testimony's admission amounted to more than harmless error. *Argentine v. United Steelworkers of America*, 287 F.3d 476, 486 (6th Cir. 2002).

The critical question for the jury in this case was whether Dr. Anderson administered the standard of care to Tina Field that a reasonable physician under similar circumstances would have administered. Each side presented three medical expert witnesses concerning Dr. Anderson's standard of care. Having reviewed the record, it is clear that the district court's admission of the Vanderbilt physicians' statements was highly prejudicial because it enabled Dr. Anderson to introduce two additional expert opinions vouching for his standard of care. Yet unlike the other expert witnesses, the Vanderbilt physicians' identities and credentials were entirely unknown and their opinions were never subject to cross-examination.

Of greatest concern to this Court is that the Vanderbilt physicians' statements **[*17]** were the strongest evidence at trial that Dr. Anderson might have provided Tina Field with proper care because they were made while that care was being administered. That is, unlike the other medical experts who testified at trial by opining retrospectively on a cold record, Dr. Anderson's testimony about the Vanderbilt physicians' statements permitted him to convey the highly prejudicial impression that Tina Field was essentially being treated by a team of three doctors, two of whom were held out to the jury to be experts from the Vanderbilt University Medical Center.

We have noted that HN6 "in close cases the improper admission of prejudicial evidence is all the more damaging." *Mitroff v. Xomox Corp.*, 797 F.2d 271, 277 (6th Cir. 1986). Here, there is little doubt that the substance of the statements, combined with the air of prestige and expertise attributed to their anonymous sources, rendered them highly prejudicial to Plaintiffs' case.

Finally, we do not find, as Defendant urges us to, that the district court's jury instruction concerning the statements was curative. The court's instruction was as follows:

> THE COURT: You just heard about a telephone conversation **[*18]** with Vanderbilt. It's permissible for you to hear that, to hear the doctor's testimony as to the statements that he heard over the telephone. That's proper for you to consider that. That's not proper to consider whether-the information received is not proof of the validity of the advice given, but it is proper for you to consider the testimony that there was a conversation with these people at Vanderbilt. That's a matter for you to consider. Thank you.
>
> Given the instruction's patently jumbled and confusing nature, we are certain that no juror would have properly understood it to prohibit his or her consideration of the substance of the Vanderbilt physicians' statements.

The dissent dismisses the possibility of prejudicial error by presuming that Plaintiffs "must have been satisfied with the district court's wording of the admonition," since Plaintiffs "failed . . . to suggest a clearer admonition or later instruction to the jury." First of all, as a legal matter, Plaintiffs were not required to object to the admonition in order to preserve their claim of error concerning

the Vanderbilt physicians' statements. HN7↑According to Rule 103(a)(2) of the Federal Rules of Evidence **[*19]** , "once the court makes a definitive ruling on the record admitting or excluding evidence, either at or before trial, a party need not renew an objection . . . to preserve a claim of error for appeal." Plaintiffs properly preserved their claim of error when-during the side-bar discussed above-they objected to the statements' admission on hearsay grounds. Secondly, as a factual matter, Plaintiffs' counsel did attempt to discuss the admonition with the judge, at the side-bar. Plaintiffs' counsel, Mr. Myers, stated: " I think the jury ought to be given an admonition [that] what Vanderbilt has told him [i.e. Dr. Anderson] is not to be considered for . . . purposes of determining whether that's appropriate care or not." It was the trial judge who then prevented any further discussion about the admonition by responding: "Let me pass on that one when it's coming in." Realizing that the Vanderbilt statements would be presented imminently, Mr. Myers quickly rejoinded: "I think [Defendant's counsel is] getting ready to [elicit the statements] right now." The judge was unresponsive to this apparent second attempt to discuss the admonition and directed the examination of Dr. Anderson to **[*20]** continue. Nevertheless, Mr. Myers's efforts were hardly those of a passive or acquiescent counsel, as the dissent suggests.

For those reasons, we hold that the erroneous admission of the statements was not harmless error.

III. CONCLUSION

For the foregoing reasons, we VACATE the jury's verdict and REMAND this case to the district court for a new trial. Defendant's cross-appeal challenging the district court's denial of attorneys' fees and costs is, therefore, moot, and DISMISSED.

DISSENTBY: SILER

DISSENT:

SILER, Circuit Judge, dissenting. I agree with the majority's conclusion that the admission of the statements from the two persons at the Vanderbilt Hospital to Dr. Anderson were hearsay. However, I would affirm the decision by the district court, because the error was harmless.

The majority recognizes that Dr. Anderson's testimony that he sought the advice of an emergency room doctor and toxicologist at the Vanderbilt Medical Center was properly admitted. It was the substance of the conversation between Dr. Anderson and the Vanderbilt physicians that was improperly admitted over an objection. However, the district court's admonition to the jury immediately following the admission of **[*21]** that testimony focused on that point. The majority criticizes the court's admonition to the jury, but the admonition was given with the approval of Field's lawyer and no objection or substitute version of the admonition was presented to the court to correct any ambiguity in the language. Moreover, Field's counsel did not tender any instruction to the jury under Fed. R. Civ. P. 51.

Although the admonition to the jury could have been couched in clearer language, the failure of counsel to suggest a clearer admonition or later instruction to the jury suggests that the error was harmless.

"An erroneous admission of evidence that does not affect the 'substantial rights' of a party is considered harmless." *United States v. Cope*, 312 F.3d 757, 775 (6th Cir. 2002). This admission of hearsay was the only assignment of error from the entire proceeding before the district court. It was made in the context of multiple expert witnesses from both sides who presented evidence of the standard of care. Testimony as to the fact of Dr. Anderson's consultation with, and his resulting reliance upon, Vanderbilt's medical experts would have been **[*22]** admissible, and the prejudicial effect of the hearsay evidence was tempered by the admonition to the jury. This admonition was for the benefit of the plaintiffs. "If the [party], having lost their argument on general admissibility, desired a more precise limiting instruction on the extent to which the jury could consider such testimony, it could, and should, have requested one." *United States v. Dozier*, 672 F.2d 531, 543 (5th Cir. 1982). As the plaintiffs were aware that it was the intent of the court to cure the improper

prejudicial effect of the hearsay evidence, they must have been satisfied with the district court's wording of the admonition. Parties cannot elect to remain silent in apparent reliance on a jury instruction until after an adverse jury verdict and then raise this issue for the first time on appeal. *See* *Segal v. Cook*, 329 F.2d 278, 280 (6th Cir. 1964).

A basic principle of the law is that juries are presumed to follow the instructions of the court. *See* *Richardson v. Marsh*, 481 U.S. 200, 206-07, 95 L. Ed. 2d 176, 107 S. Ct. 1702 (1987); *United States v. Forrest*, 17 F.3d 916, 920-21 (6th Cir. 1994). Here, the district **[*23]** court instructed the jury not to consider the statement from the Vanderbilt personnel as proof of the standard of care, but just that they gave Dr. Anderson some advice. Because counsel for the plaintiffs did not object to the admonition nor tender an alternative either at the time the admonition was made or at the time the instructions to the jury were given, the plaintiffs have to be considered satisfied with that admonition. I would presume that the jury followed the admonition of the court. Therefore, I would find that the one error at trial in admitting the statements from the persons at Vanderbilt was harmless because it was cured by the admonition.

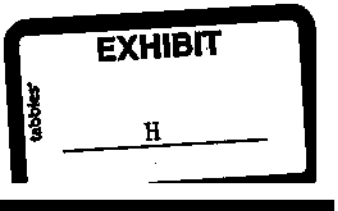
IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

LUANN PARKER, Plaintiff, v. AVENTIS PASTEUR, INC. Box 187 Discover Drive Swiftwater, Pennsylvania 13670 Defendants.	)	Case No. C-1-00-766 Judge Michael Watson **AFFIDAVIT OF WILLIAM PAUL GLEZEN, M.D.**

* * *

William Paul Glezen, being first duly sworn, deposes and says as follows:

1. I am an adult over eighteen (18) years of age. I am a medical doctor licensed to practice medicine in Texas and I am Board Certified in Pediatrics and Epidemiology. Presently, I am an Adjunct Professor of Epidemiology at the School of Public Health, University of Texas Health Science Center at Houston, and a Professor of Molecular Virology and



Microbiology at Baylor College of Medicine in Houston, Texas. My qualifications are contained in the curriculum vitae that was attached as Exhibit 1 to my initial Affidavit filed in this case.

2. During my professional career, I have studied, lectured on and written medical articles on influenza and influenza vaccines. I am also very familiar with the medical literature and the epidemiological studies concerning the potential adverse effects of influenza vaccine.

3. In 1980, H.F. Retailliau, M.D. and others published and article entitled *Illness After Influenza Vaccination Reported Through a Nationwide Surveillance System, 1976-1977* in the American Journal of Epidemiology. (A copy of the article is attached). Dr. Retailliau, who was with the Centers for Disease Control at the time, performed an epidemiological study of illnesses following influenza vaccination for over forty-eight (48) million persons vaccinated in 1976 with the swine flu influenza vaccine. Based upon his study, he found that the incidence rate for encephalitis following the receipt of swine flu influenza vaccine was less than expected in the general population. The data generated from this study demonstrated that there was no evidence that a person who received swine flu influenza vaccine was at increased risk of developing ADEM compared to a person who had not recently received influenza vaccine.

4. Beginning in 1990, adverse events data following receipt of vaccines were reported to the FDA in the Vaccine Adverse Event Reporting System ("VAERS"). Under the VAERS system, physicians, individuals and vaccine manufacturers are to report suspected adverse events following the administration of any vaccine, including influenza vaccine. Since 1990, hundreds of millions of doses of influenza vaccine have been administered in the United States. In recent years, approximately eighty (80) million doses of influenza vaccine are

distributed in any given year. The CDC monitors the incidence of reports of adverse events following these vaccinations through the VAERS system. With 80 million doses administered, it is very possible to pick up rare events. No epidemiological studies linking or associating influenza vaccine with acute disseminated encephamyelitis in any year following the 1976 influenza vaccine have been published. Moreover, the number of cases of ADEM following influenza vaccine reported through the VAERS system have been insufficient to even suggest a hypothesis that ADEM is caused by influenza vaccine. As a result, no basis for studying any association between ADEM and influenza vaccine has been established.

5. It is my medical opinion, to a reasonable degree of medical probability, that ADEM has never been causally associated with influenza vaccine. In fact, in the only published epidemiological study specifically addressing this issue, the incidence of encephalitis following swine flu influenza vaccine was less than expected in the general population. Accordingly, a cause and effect relationship has not been proven.

Further affiant sayeth naught.

William Paul Glezen

Sworn to and subscribed in my presence this 29 day of October 2004.

Notary Public

BLANCA M. PENA
Notary Public, State of Texas
My Commission Expires
February 04, 2007

COPY

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Original Contributions

ILLNESS AFTER INFLUENZA VACCINATION REPORTED THROUGH A NATIONWIDE SURVEILLANCE SYSTEM, 1976–1977

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In 1976, the Center for Disease Control coordinated nationwide surveillance for illnesses after influenza vaccination as part of an effort to vaccinate the nation against influenza A/New Jersey/76. For the 48,161,019 persons vaccinated in 1976, a total of 4733 reports of illness were received which included reports of 223 deaths. When Guillain-Barré syndrome was reported in vaccine recipients, an investigation was begun to examine this possible association. Other than the Guillain-Barré syndrome and rare cases of anaphylaxis, no serious illnesses were causally associated with influenza vaccination by this type of surveillance. Widespread underreporting of illness and death in the passive phase of this surveillance system, however, impaired the ability to draw conclusions about reactions to vaccine from the reports of illness received.

Guillain-Barré syndrome; influenza; influenza vaccine

In 1976, the US Federal government sponsored the National Influenza Immunization Program that sought for the first time to immunize not only those at high risk for influenza but also most healthy adults and children. In 1976–1977, mostly between October 1 and December 16, 1976, 46,651,113 civilians and 2,509,906 military personnel were vaccinated against influenza A/New Jersey/76.

Before the vaccine administration began, a nationwide surveillance system was established to evaluate illnesses that would be temporally associated with influenza vaccination. No previous mass immunization campaign included a similar prospective surveillance network with participation by all state and territorial health departments. The surveillance was designed to rapidly identify illnesses temporally related to vaccination, so that appropriate investigation could determine their importance. This paper reviews the surveillance system and the reports received by the Center for Disease

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Abbreviations: CDC, Center for Disease Control; GBS, Guillain-Barré Syndrome; ICDA, International Classification of Diseases, Adapted; SAC, Surveillance and Assessment Center.

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Control (CDC) from October, 1976, through January, 1978.

Methods

The surveillance system for evaluation of illness temporally associated with influenza vaccination included a passive reporting system centrally coordinated by the CDC Surveillance and Assessment Center (CDC-SAC) and initiation by CDC or state health departments of active follow-up of serious illnesses. All state and territorial health departments were required to participate in this surveillance effort in order to administer vaccine. A report form covering basic epidemiologic information was developed by CDC and distributed to all state health departments to assist in uniform collection and reporting of epidemiologic data. In addition, any illness serious enough to require hospitalization was to be telephoned to CDC (1). A registration form granting consent for vaccination had to be signed by all individuals vaccinated in public clinics. This form emphasized that as with all medication, influenza vaccination entailed the risk of minor side-effects such as fever in the 48 hours following vaccination and the potential risk, largely unknown, of serious side-effects or even death. This registration form allowed health departments to verify the date, type, manufacturer, and lot number of vaccines involved in reaction reports. The registration form also gave guidelines to the vaccinated individuals who wished to file claims for injury with the government.

Guidelines for reporting illness temporally related to influenza vaccination were sent by CDC to all state and local health departments (1). The definition of a reportable adverse reaction in these guidelines was as follows: "For purposes of reporting, an adverse reaction is defined as an illness occurring after influenza vaccination in which 1) the patient was ill enough to require hospitalization (e.g., anaphylaxis, encephalitis) or 2) the patient was ill enough to require bed care or an outpatient visit by the vaccinee to a public or private health facility" (1). So that events occurring long after vaccination would not be missed, no time limit was specified for the interval between vaccination and onset of illness for purposes of reporting. While a few state health departments also carried out active surveillance for reactions by sampling vaccine recipients or private physicians, reporting of an "adverse reaction" was almost always initiated by a vaccine recipient, by the recipient's family or by his or her physician contacting a health department or CDC.

CDC-SAC collected and evaluated vaccine reaction reports using an online computerized data system. Reports of reaction could be continually updated and information rapidly retrieved. The major diagnosis and symptoms along with basic epidemiologic information were recorded on computer for each report. The diagnosis was coded by a medical records technician according to the 8th revision of the International Classification of Diseases Adapted (ICDA) for the United States. In addition, CDC-SAC collected data on the number of persons vaccinated each week during the immunization program and received monthly tabulations on the age of vaccinees from state and territorial health departments. With this information, rates of reported illness per 100,000 vaccinees were calculated. Background levels of illness and death in the general population were derived from the general medical literature or from National Center for Health Statistics data (2–4). Rates of reported illness were compared with "expected" rates as a screening measure in analyzing the surveillance data as they were reported.

Results

Data on vaccine administration were received from all 57 participating state

and territorial health departments. Only three areas, Guam, Nevada and Wyoming, reported no illness at all among vaccine recipients. No geographic pattern was observed among the remaining states and territories. For illness occurring at any time following immunization, 36 states reported rates of less than five per 100,000 vaccinees, and only three states reported rates over 25 per 100,000, ranging from 32.3 to 50.3 per 100,000 vaccinees.

The rates of the reports varied considerably by age group and by the categories of reports, as shown in table 1. While the rate of reported deaths per 100,000 persons vaccinated increased with age, nonfatal illnesses were more commonly reported among younger age groups, particularly in the military population. Considerable underreporting of both deaths and nonfatal illnesses is evident from these figures. While the rate of deaths reported was 0.47 per 100,000 vaccinees at any time following vaccination, the crude death rate from all causes for the United States is 5.20 per 100,000 population for a two-day period alone, based on 1972 data available in 1976 (2). The rate of medically attended illness per 100,000 persons in the United States during 1976 has been estimated as 328 per 100,000 population per day, while only 5.9 medically attended illnesses were reported per 100,000 civilian influenza vaccine recipients at any time following the influenza vaccination (3).

Two major time trends were noted among reported deaths and illnesses, as shown in figure 1. The first is that the interval between vaccination and onset of symptoms was generally less than two days. Only 9.4 per cent of reported deaths were after an interval of greater than one week between the immunization and the onset of symptoms. The second major trend is that reports of illness and death among persons vaccinated decreased steadily from October through December 16, 1976 (at which time vaccinations were halted)—although vaccine administration increased steadily during the same period. It was reported that 21.4 per cent of the vaccine was administered in October, but that 66.4 per cent of the vaccinees who died had been immunized during October. Conversely, 39.5 per cent of vaccine was reported to have been administered during December, while only 5.4 per cent of vaccinees who died had been immunized during December. It could not be determined from the passive surveillance data whether this trend could be attributed to the effects of publicity, to a higher proportion of October vaccinees being chronically ill, or to other factors.

TABLE 1

Number and rate per 100,000 vaccinees of illness reports, by age and category, after vaccination against influenza A/New Jersey/76, United States, October–December 16, 1976

Age (years)	Deaths		Civilian illness		Military illness	
	No. of reports	Rate	No. of reports	Rate	No. of reports	Rate*
≤17			67	7.1	22	84.7
18–24	2	0.03	380	6.2	1410	116.9
25–44	15	0.11	895	6.1	349	33.5
45–64	62	0.41	816	5.5	27	13.9
≥65	143	1.65	485	5.4	5	24.9
Unknown	1		37		17	
Total	223	0.47	2680	5.9	1830	55.0

* These rates were estimated from the total number of military personnel vaccinated, using the age breakdown which was reported for 39.7% of those vaccinated.

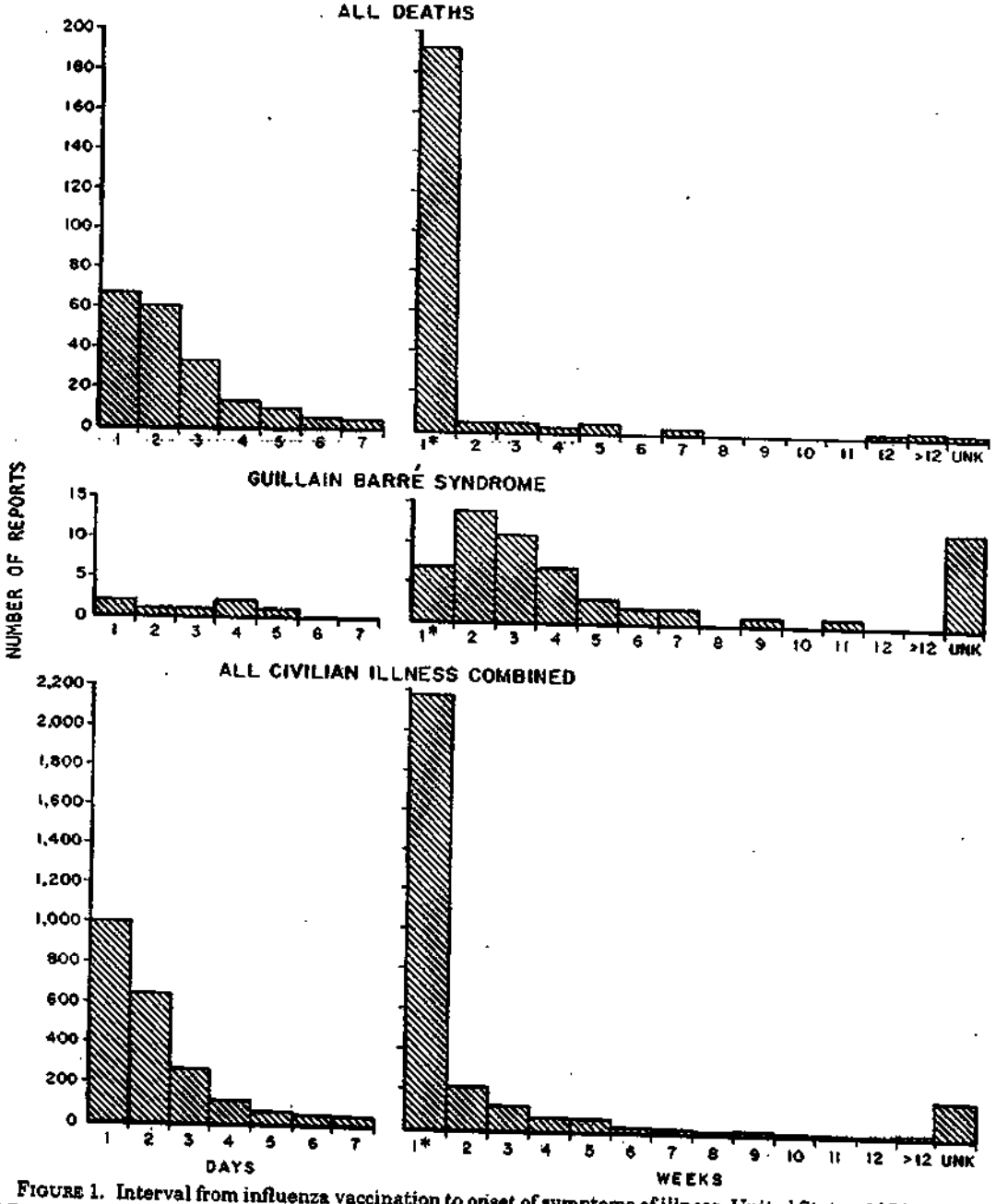

FIGURE 1. Interval from influenza vaccination to onset of symptoms of illness, United States, 1976–1977.
*Total for first week.

Delayed reports of vaccine administration may account for a portion of the trend, but cannot account for all of it.

The cause of death was obtained for all fatalities reported. These causes represented 55 ICDA codes; for 38 causes, only one death was reported, but for 17 causes, two or more deaths were attributed to the same cause (table 2). These 17 causes account for 83 per cent of deaths reported.

TABLE 2

Diagnosis reported as a cause of two or more deaths after vaccination against influenza A/New Jersey/76, United States, October–December 16, 1976

Diagnosis	No. of cases reported	Rate per 100,000 vaccinees	Crude expected death rate for a two-day period*
Acute myocardial infarction with mention of hypertension	83	0.17	0.786
Chronic ischemic heart disease without mention of hypertension	23	0.05	0.585
Congestive heart failure	12	0.02	0.037
Acute cerebrovascular disease without mention of hypertension	10	0.02	0.153
Acute myocardial infarction with hypertension	8	0.02	0.079
Cardiac arrest	8	0.02	0.026
Chronic ischemic heart disease with hypertension	6	0.01	0.345
Unspecified arrhythmia	5	0.01	0.003
Generalized arteriosclerosis	5	0.01	0.082
Aortic aneurysm	5	0.01	0.009
Pneumonia	4	0.01	0.062
Myocardial insufficiency	3	0.01	0.003
Abdominal aortic aneurysm	3	0.01	0.017
Pulmonary embolism	3	0.01	0.031
Emphysema	3	0.01	0.052
Other ischemic heart disease	2	0.004	0.011
Unknown	3	0.01	0.026

* Derived from rates for the same ICDA codes per 100,000 population. Tables 1–23, Volume II, Part A, Mortality, Vital Statistics of the United States, National Center for Health Statistics, 1974.

The commonly reported diagnoses reflect almost exclusively chronic disease processes which have a sudden episode as the terminal event. Since almost two-thirds of the reported deaths occurred in individuals who had onset of symptoms within 48 hours of vaccination, the rates derived from NCHS data per 100,000 population for a two-day period are noted in table 2 as an "expected" rate of deaths for comparison purposes. While several deaths were reported to be due to central nervous system disease, autopsy ruled out the possibility of allergic encephalitis in all but one, a case in which perivascular demyelination was reported.

In the second week of October, three deaths from cardiovascular causes were noted in chronically ill persons over 71 years of age vaccinated in one Pennsylvania vaccination clinic. A team of epidemiologists from CDC and from the Pennsylvania State Health Department investigated these deaths and was unable to establish a causative link between immunization and the deaths (5). Persons vaccinated in the clinic died at a rate of 5/100,000/day in contrast to the expected rate of 17/100,000/day for persons 65 years and older in Pennsylvania (5).

Among ill civilian vaccinees who did not die, 283 different ICDA code illnesses were diagnosed. (The list is available on request from CDC as it is beyond the scope of this paper.) The categories encompassing ill-defined conditions and unspecified reaction to vaccine account for 65 per cent of the diagnoses reported. The symptoms associated with this group of reports were fever (42 per cent), headache (36 per cent), malaise (29 per cent), and myalgia (25 per cent), pain (13 per cent),

and dizziness (10 per cent). Allergic symptoms such as rash (80 cases) and hives (42 cases) were reported at a rate of 0.3 per 100,000 but more serious illnesses such as anaphylaxis (11 cases) were rare. While all the cases reported as anaphylaxis occurred within 24 hours of vaccination, most began more than 15 minutes following vaccination and prior sensitivity to eggs was reported in none of the cases. Syncope (62 cases) was commonly reported immediately following immunization. Seizures were occasionally reported (19 cases), most often occurring within minutes of vaccination, but most were not clearly differentiated from abnormal movements that are commonly associated with syncope. A small group of illnesses were reported that may have been related to the vaccination procedure itself and this included 33 cases of hysteric reactions, and 13 reports of infection at or near the vaccination site. An additional 25 cases of physical injury resulting from movement within an immunization clinic or from the injection itself were reported.

While most of the follow-up of case reports of illness by state health departments uncovered no evidence to link influenza vaccination with the illness reported, the cases of Guillain-Barré syndrome (GBS) were an exception. By December 2, 1976, seven cases of GBS in two clusters had been reported to CDC-SAC. The incidence of GBS among vaccinees in both states first reporting this syndrome was higher than expected when compared to incidence figures for GBS in the medical literature (6). This finding led to an intensive active investigation involving all 50 states to determine if this association was more than coincidence (7–9). While 61 cases of GBS were reported through the routine surveillance system, the presence of an alternate reporting system through a widely publicized active surveillance campaign makes it difficult to compare these cases with other illnesses reported through the routine surveillance system. Figure 1 compares the interval between vaccination and onset of symptoms for GBS, all civilian illnesses and all deaths. No disease other than GBS was reported more commonly in the second and third week than in the first week.

A wide variety of neurologic syndromes were reported in addition to GBS. The active investigation on GBS involved contacting all practicing neurologists and this probably led to better reporting of neurologic illness after vaccination than nonneurologic illness (8). Although some neurologic reports were filed on forms designed for the GBS investigation, in retrospect it is not possible to exactly quantitate the effect of this separate investigation on the reporting of neurologic illnesses after vaccination. The most common neurologic syndromes reported were facial paralysis (26 cases), other or unspecified neuritis (26 cases), encephalitis (18 cases), peripheral nerve disease (16 cases), brachial neuritis (9 cases), optic neuritis (8 cases), demyelinating disease (5 cases), and labyrinthitis (5 cases). Other central nervous system inflammatory diagnoses included five cases of meningitis, four cases of viral encephalitis, one case of encephalopathy, and one case of post vaccinal encephalitis. The rates of each of these syndromes were lower than "expected" rates derived from data in the medical literature extrapolated to two-day periods. The rate of all encephalitic or meningitic processes together was 0.07 per 100,000 vaccinees from one to 90 days after vaccination. In comparison, encephalitis and aseptic meningitis alone are passively reported to CDC at a rate of 0.20 per 100,000 population in a four-week period for the United States (10). One state reported four cases of encephalitis, a rate of 0.14 cases per 100,000 vaccinees within four days of vaccination. No other regional clusters of encephalitis were reported.

Discussion

The reaction surveillance system described above was a success in that a large

scale investigation into the association between GBS and influenza vaccination was begun when health authorities had learned of only seven cases nationwide. A system designed as an early warning system, where illness rates among vaccinated persons could be rapidly estimated, was crucial in the initial investigation of GBS in vaccinees. The proof of an association required a quite different approach than the combined passive and limited active surveillance used as the initial screening technique for illnesses reported in persons vaccinated against influenza (9). Nonetheless, even in the passively acquired initial data, GBS contrasted with all other illnesses reported by being reported at a higher rate than reported background rates, and by being more commonly reported in the second and third weeks following vaccination than in the first week (figure 1) (6).

Reports of illness that depend on voluntary reporting during a time of varying publicity are inappropriate for retrospectively developing rates of illness in a target population. Although such reports were crucial in uncovering an association of GBS with vaccination, an examination of the data in table 2 quickly reveals some of the problems involved in retrospectively using these data as an estimate of true rates of occurrence of illness in the vaccinated population. First, the causes of death reported reflect mostly those causes that involve a rapid terminal event to a chronic illness, and less dramatic causes of death are conspicuously absent. Second, underreporting of even deaths was so striking that those deaths reported can only represent a very biased selection from which no valid extrapolation to rates can be made. Third, while an "expected" death rate for a two-day period is noted in table 2 for the most commonly reported causes of death, an argument can be made against almost any source of "expected" rates as not comparable with the vaccinated population in such crucial epidemiologic parameters as age, prior illness experience and exposure to medical care. In addition, the reporting of illnesses following influenza vaccination was not limited to any specific time limit with respect to the interval between vaccination and the onset of symptoms. One should note too that illnesses which as a rule occur rarely, but which occur commonly following immunization would be very likely to be detected, but a slight increase in commonly occurring illnesses induced by vaccination would probably not be detected (11).

The passively reported data gathered through this surveillance system are of such a nature that they cannot be compared with data gathered from monitored defined populations. Bruising, pain or bleeding at the injection site were all reported. These did not generally require medical care and—not meeting the definition of a reportable reaction—their frequency cannot be estimated from the data reported through this surveillance system. More accurate estimates of this type of minor reaction were sought through extensive vaccine trials and individual studies involving thoroughly monitored study populations (12, 13). None of the participants in the vaccine trials were reported to have had serious reactions to influenza vaccination while minor illness or fever following immunization occurred in an age dependent percentage of vaccine recipients (13).

Allergic skin diseases were reported at a rate of 0.3 per 100,000 vaccinees. Severe allergic reactions such as anaphylaxis were reported at a rate of 0.024 per 100,000 vaccinees in comparison to 40 per 100,000 doses found earlier when penicillin was administered in a national survey (14). Syncope, hysteric or other psychologic reaction, infection and trauma sustained from movement in or near a vaccination clinic were reported through the routine surveillance system; these events can be interpreted as side ef-

fects of vaccine administration and can be anticipated in any mass immunization campaign regardless of the antigens being administered. But to determine a rate of occurrence of these illnesses in association with vaccination would require the simultaneous monitoring of very large populations of vaccinated individuals and a comparable population of unvaccinated persons.

A cluster of four encephalitis cases within a week of vaccination was noted in one state for a rate of 0.14 per 100,000 persons immunized, a rate higher than that expected for the general population for a one-week period. It should be noted that encephalitis reported following smallpox vaccination usually occurs at an interval of 10 to 14 days following immunization (15, 16). Three case reports of encephalitis occurring after influenza immunization have appeared with a time interval of four days or less (17). However, encephalitis and other neurologic illnesses followed the same trend as all other illnesses reported (GBS excepted) in that most of the reported cases had onset in the first few days following vaccination and overall reports were at very low rates.

If improving our knowledge of rates of illness caused by vaccination is considered an important objective during future immunization campaigns, then certain conclusions can be drawn from the surveillance system and the data that were generated as a result of the 1976 influenza immunization campaign. First, passive surveillance with the ability to actively investigate when required, has a role in uncovering the unexpected or unusual reactions to vaccination. Second, a centrally coordinated program that is able to keep track of reports from different areas as well as information on vaccine administration is crucial in the evaluation of reports of reaction to vaccine. Third, in addition to a passive surveillance system depending on the cooperation of informed private physicians, a surveillance method that allows for complete case ascertainment for comparable vaccinated and unvaccinated populations could prove very useful. Such a prospective system need not be nationwide nor deal with the entire spectrum of human illness. Surveillance through particular groups such as practicing neurologists or through hospital emergency rooms could be part of the sampling techniques to avoid making the cost of such surveillance prohibitive. While the variety of illnesses reported following influenza vaccination in 1976 in itself argues against a causal connection between the vaccination and most illnesses, it presents a formidable obstacle for the identification of those few illnesses that could be associated with vaccination but have not as yet been identified.

Future immunization programs could benefit greatly from an analysis of the patterns of reporting observed during the 1976 influenza vaccination program. The wide disparity in the reporting behavior of adjacent states suggests that differences in technique and interpretation of common guidelines were important factors. The techniques used in areas where reporting was more complete should be further analyzed to see if they could be more efficiently used elsewhere as well during future campaigns. It is too easy for public health personnel and epidemiologists to dismiss the entire influenza immunization program of 1976. Valuable lessons remain to be learned from closer examination of many of the aspects of the program, particularly in the area of monitoring for reactions to vaccine (18).

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